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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,018	07/07/2003	Ursula-Henrike Wienhues	2923-543	8627

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EXAMINER

STEELE, AMBER D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,018	Applicant(s) WIENHUES ET AL.	
	Examiner Amber D. Steele	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

1. Claims 1-24 are currently pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15 and 19-22 are drawn to a method for the detection of an antibody, classified in class 435, subclass 7.1.
 - II. Claims 16-18 are drawn to a reagent for the detection of an antibody, classified in class 436, subclass 518.
 - III. Claim 23 is drawn to an antigen of formula 1a, classified in class 530, subclass 403.
 - IV. Claim 23 is drawn to an antigen of formula 1b, classified in class 530, subclass 300.
 - V. Claim 24 is drawn to an antigen of formula $P^1\{P^2[P^3(P^4)]_t\}_s$, classified in class 530, subclass 350.
3. The inventions are independent and/or distinct, each from the other because of the following reasons:
 - A. Inventions II-V are drawn to independent and/or patentably distinct products since these products have different chemical structures and/or functions. For example, Group II requires a solid phase wherein Groups III-V do not require a solid phase, Group III consists of an antigen of formula 1a wherein Groups IV-V do not consist

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of an antigen with a formula of 1a, Group IV consists of an antigen of formula 1b wherein Groups III and V do not consist of an antigen with a formula of 1b, and Group V is an antigen with the formula $P^1 \{P^2[P^3(P^4)_t]_s\}_r$ wherein Groups II-IV do not require this formula. Therefore, Groups II-V have different issues regarding patentability and enablement. Additionally, Groups II-V represent patentably distinct subject matter which merits separate and burdensome searches. Art anticipating or rendering obvious Group II would not necessarily anticipate or render obvious Groups III-V or *vice versa*, because they are drawn to different inventions that have different distinguishing features. Furthermore, Groups II-V have a separate status in the art as shown by the different classification (e.g. subclass or class; please refer to section 2).

B. Inventions II-V and I are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be utilized in a method of eliciting an immune response.

4. Because these inventions are distinct for the reasons given above and:
 - a. have acquired a separate status in the art as shown by their different classification (please refer to paragraph 1), and/or
 - b. divergent subject matter which would require different bibliographic and/or classification searches; and/or

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c. because the inventions have acquired a separate status in the art because of the recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

5. This application contains claims directed to the following patentably distinct species of the claimed inventions for Groups I-V. Election is required as follows.

6. If applicant elects the invention of **Group I**, the applicant is required to elect a single, specific species from **each** of the following species A-D.

A. species of pathogenic organism

Applicant must elect, for the purposes of search, a **single, specific species** of pathogenic organism.

B. species of hapten

Applicant must elect, for the purposes of search, a **single, specific species** of hapten.

C. species of carrier

Applicant must elect, for the purposes of search, a **single, specific species** of carrier.

D. species of "P"

Applicant must elect, for the purposes of search, a **single, specific species** of "P".

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome

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manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

7. If applicant elects the invention of **Group II**, the applicant is required to elect a single, specific species from **each** of the following species.

species of "P"

Applicant must elect, for the purposes of search, a **single, specific species** of "P".

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

8. If applicant elects the invention of **Group III**, the applicant is required to elect a single, specific species from **each** of the following species.

species of "P"

Applicant must elect, for the purposes of search, a **single, specific species** of "P".

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome

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manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

9. If applicant elects the invention of **Group IV**, the applicant is required to elect a single, specific species from **each** of the following species.

species of "P"

Applicant must elect, for the purposes of search, a **single, specific species** of "P".

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

10. If applicant elects the invention of **Group V**, the applicant is required to elect a single, specific species from **each** of the following species.

species of "P"

Applicant must elect, for the purposes of search, a **single, specific species** of "P".

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome

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manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, **including any claims subsequently added**. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicant traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicant to request an oral election was not made. See MPEP § 812.01.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996. Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to a rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Future Correspondences

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS

December 28, 2005



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